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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,941	03/01/2004	Joseph Miller	S63.2-10812-US01	2180
	7590 06/18/200 TT & STEINKRAUS,	EXAMINER		
6109 BLUE CI	·	COZART, JERMIE E		
SUITE 2000 MINNETONK	A, MN 55343-9185	ART UNIT	PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)				
	10/790,941	MILLER ET AL.				
Office Action Summary	Examiner	Art Unit				
	Jermie Cozart	3726				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 20 Ma	arch 2007.					
2a)⊠ This action is FINAL . 2b)☐ This	action is non-final.					
3) Since this application is in condition for allowar						
closed in accordance with the practice under E	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims	•					
4)⊠ Claim(s) 1-12 and 20-27 is/are pending in the a	☑ Claim(s) 1-12 and 20-27 is/are pending in the application.					
4a) Of the above claim(s) is/are withdray	4a) Of the above claim(s) is/are withdrawn from consideration.					
5)⊠ Claim(s) <u>3</u> is/are allowed.	, , , , , , , , , , , , , , , , , , , ,					
6) Claim(s) 1, 2, 4-12 and 20-27 is/are rejected.	; • —					
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	r election requirement.					
Application Papers						
9) The specification is objected to by the Examine	r.					
10)☐ The drawing(s) filed on is/are: a)☐ acce	epted or b) objected to by the l	Examiner.				
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correct						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119		•				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:					

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 1, 2, 4, 5, 7-11, 20-22, and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Ching et al. (US 6,481,262 B2).

Regarding <u>claims 1</u>, Ching discloses positioning assembly of a crimper apparatus (10) comprising a first plate (50) and a second plate (20), the first plate having a nest (1n; see FIG. 2 below) located between ribs (44) to accommodate at least a portion of a first cylindrical member (60), the second plate (20) having a nest (2n; see FIG. 2 below) located between ribs (24) to accommodate at least a portion of a second cylindrical member (61). The first nest (1n) and the second nest (2n) aligned along the longitudinal axis (see FIG. 6). The first plate (50) constructed and arranged to be separated from the second plate (20) in a first position. The first plate (50) and the second plate (20) are moveable relative to one another (col. 4, lines 26-30) in the longitudinal direction [see Fig. 2, i.e. the first plate (50) is inserted first and placed in member (30) then the second plate (20) is moved longitudinally so as slide above plate (50) is inserted first and placed in member (30) is inserted first and placed in member (30) then the second plate (20) is moved longitudinally so as slide above plate (50) into groove (34) of member (30)] the first plate (50) into groove (34) of member (30)] the first plate longitudinally so as slide above plate (50) into groove (34) of member (30)] the first plate

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(50) is constructed and arranged to be separated from the second plate (20) in the longitudinal axis and in a second position (see fig. 1) the first plate (50) closer to the second plate (20) than in the first position, when in the second position the first plate (50) and the second plate (20) situated such that the first cylindrical member and the second cylindrical member would be in predetermined placement for joining.

Regarding <u>claim 2</u>, the first plate (50) has a nest (described above, see also fig. 6) longitudinally aligned with a nest (described above, see also fig. 6) on the second plate (20):

Regarding <u>claim 4</u>, a first biasing member (i.e. user/operator's hands) biases the first plate (50) toward the first position when activated

Regarding <u>claim 5</u>, a second biasing member (52) biases the first plate (50) toward the second position when the first biasing member is not activated.

Regarding claim 7, the second biasing member comprises a spring (52).

Regarding <u>claim 8</u>, the second plate (20) further comprises a third nest (3n), the third nest (3n) offset from the second nest (2n) in a direction lateral to longitudinal axis.

Regarding <u>claim 9</u>, the second plate (20) is moveable prior assembly within the fixture (30) to align the third nest (3n) with the first nest (1n) along the longitudinal axis.

Regarding <u>claim 10</u>, the first cylindrical member is a stent retaining member (not labeled, see fig. 6).

Regarding <u>claim 11</u>, the second cylindrical member is a catheter tube (60).

Regarding <u>claim 20</u>, Ching discloses a first plate (50) and a second plate (20), the first plate having a first nest (1n) to accommodate at least a portion of the catheter,

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the second plate (20) having a second nest (2n) to accommodate at least a portion of the marker (i.e. stent). The first plate (50) moveable relative the second plate (20) along the length of the catheter between the first and second positions, the first plate (50) biased toward one of the positions. Note that the catheter and marker are not part of the positioning assembly, therefore these limitations (i.e. catheter and marker) have not been given patentable weight because the claim is solely directed to a "positioning assembly" and not the combination of a positioning assembly, catheter, and marker.

Regarding <u>claim 22</u>, Ching discloses a first plate (50) and a second plate (20), the first plate (20) having a first nest (1n) to accommodate at least a portion of the catheter (60), the second plate (20) having a second nest (2n) to accommodate at least a portion of the marker (i.e. stent). The first plate (50) and second the second plate (20) moveable relative to one another to adjust a distance between the first nest (1n) and the second nest (2n) as measured along the length of the catheter (60). Note that the catheter and marker are not part of the positioning assembly, therefore these limitations (i.e. catheter and marker) have not been given patentable weight because the claim is solely directed to a "positioning assembly" and not the combination of a positioning assembly, catheter, and marker.

Regarding <u>claim 24</u>, the first plate (50) further comprising a fourth nest (4n), the fourth nest (4n) offset from the first nest (1n) in a direction lateral to the longitudinal axis.

Regarding <u>claim 25</u>, the first plate (50) is moveable to align the fourth nest (4n) with second nest (2n) along the longitudinal axis prior to being positioned in the fixture (30).

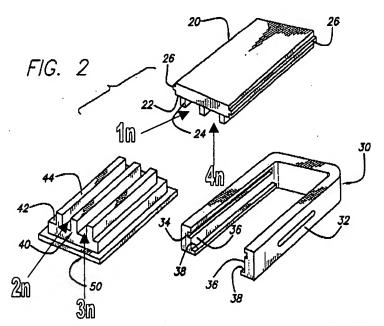
Regarding <u>claim 26</u>, the fist plate (50) contacts the second plate (20) when in the second position (i.e. wherein the second position can also be also defined as the first plate and second plate being assembled in fixture 30 within the catheter assembly therein such that biasing force of springs (52) place the first plate and second plate in contact).

Regarding <u>claim 27</u>, the third nest (3n) is coaxially aligned with the first nest (1n). See column 3, line 64 – column 5, line 12, and figures 1, 2, and 6 for further clarification.

Note that the recitation "for automatically positioning a second cylindrical member for crimping to a first cylindrical member, the first cylindrical member defining a longitudinal axis" and "for automatically positioning a marker for crimping a catheter" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Note also that for the purposes of the above rejection, the longitudinal direction of the cylindrical members and the plates have been treated as being different, since the claims are directed solely to the positioning assembly and not the combination of the positioning assembly and first and second cylindrical members.

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Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 6, 12, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ching et al. (US 6,481,262 B2).

Ching discloses the first cylindrical member being a catheter tube.

Ching, however, does not expressly disclose the second cylindrical member being the inner tube of a catheter. Ching also does not disclose the first biasing member being at least one solenoid. Ching also does not disclose the second nest and the third nest having different geometries.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use at least one

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solenoid as the first biasing member, to form the second cylindrical member as the inner tube of a catheter, and to provide the second and third nests with different geometries because Applicant has not disclosed that using at least one solenoid as the first biasing member, the second cylindrical member being the inner tube of a catheter, or the second and third nests have different geometries provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the second and third nests having the same geometry, the first biasing member being the hand of the operator/user, and the second cylindrical member being a catheter tube because the user/operator's hand maintains the first position when activated and the first cylindrical member is fixedly secured on the catheter tube.

Therefore, it would have been an obvious matter of design choice to modify

Ching to obtain the invention as specified in claims 6, 12, and 23.

Response to Arguments

5. Applicant's arguments filed 3/20/07 have been fully considered but they are not persuasive.

Applicants argue that Ching does not teach a plate that is moveable along the longitudinal axis of the catheter (60).

In response, the Examiner maintains that for the purposes of the above rejection with respect to Ching, the longitudinal direction of the plates (see Figs. 2 an 6) have been treated as being different because the claims are directed solely to the positioning

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assembly and not the combination of the positioning assembly and first and second cylindrical members. In Fig. 5 of Ching, both the first cylindrical member and the second cylindrical member have a longitudinal axis extending in a longitudinal direction. In Fig. 2 of Ching, the first plate (50) and the second plate (20) are moveable relative to one another (col. 4, lines 26-30) in the longitudinal direction [see Fig. 2, wherein the first plate (50) is inherently inserted first and placed in member (30) then the second plate (20) is moved longitudinally so as slide above plate (50) into groove (34) of member (30)]. Therefore, both the first cylindrical and the second cylindrical member have a longitudinal axis extending in a longitudinal direction which is separate and distinct from the first plate and the second plate that are moveable relative to one another in the longitudinal direction as described above in detail.

Applicants argue that Ching similarly does not teach a plate that is moveable along the length of the catheter.

In response, the Examiner maintains that the catheter does not form part of the claimed invention as the claims are solely directed to a positioning assembly which does not either the catheter or marker. The catheter and marker have been incorporated into the preamble of the claims and also serve merely as functional recitations in the remainder of the claim.

Applicants also argue that the rejection provides no prior art to modify Ching in a way that would result in a device meeting the limitations of the rejected claims.

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In response, the Examiner acknowledges that there was no prior art provided to modify the device of Ching because the claims have been anticipated under 35 U.S.C. 102(b) and stand alone with Ching under 35 U.S.C. 103(a).

Allowable Subject Matter

- 6. Claim 3 is allowed.
- 7. The indicated allowability of claims 20-22 is withdrawn in view of Ching because Applicant's present amendment broadened the scope of claims 20-22 and thereby Ching anticipates the claims under 35 U.S.C. 102(b).

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jermie Cozart whose telephone number is 571-272-4528. The examiner can normally be reached on Monday-Thursday, 7:30 am - 6:00 pm.

- 10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Bryant can be reached on 571-272-4526. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
- 11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JERMIE E. COZART PRIMARY EXAMINER